

Compatibility (EMC) of Electrically-Powered Medical Devices” (2016 EMC guidance), which was published July 11, 2016. This guidance provides additional technical information to address the recommendations in the 2016 EMC guidance.

FDA recognizes and anticipates that the Agency and industry may need up to 1 year to perform activities to operationalize the policies within the guidance, *only* for in vitro diagnostic products. Because this guidance generally reflects current practice for the assessment of EMC for other device types, but some activities to fully operationalize the policies are needed (e.g., updates to eSTAR¹), FDA intends to implement this guidance 60 days after issuance for device types within the scope of this guidance, excluding in vitro diagnostic products. If new information regarding electromagnetic compatibility as outlined in this guidance is not included in a premarket submission for an in vitro diagnostic received by FDA before or up to 1 year after the publication of this guidance or for other device types within the scope of this guidance before or up to 60 days after the publication of this guidance, FDA does not generally intend to request such information during the review of the submission. FDA does, however, intend to review any such information if submitted.

A notice of availability of the draft guidance appeared in the **Federal Register** of November 17, 2020 (85 FR 73276). FDA considered comments received and revised the guidance as appropriate in response to the comments, including clarification of scope; addressing the use of IEC 60601–1–2:2020, which was published after the draft guidance was issued; and adding a transition period to facilitate the implementation of the guidance.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on EMC of medical devices. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products> or from the

Center for Biologics Evaluation and Research at <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>. This guidance document is also available at <https://www.regulations.gov> and <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. Persons unable to download an electronic copy of “Electromagnetic Compatibility (EMC) of Medical Devices” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400057 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073

Dated: May 31, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–12099 Filed 6–3–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections

552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities.

Date: June 28–29, 2022.

Time: 9:00 a.m. to 8:00 p.m.

¹ Available at <https://www.fda.gov/medical-devices/premarket-notification-510k/voluntary-estar-program>.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Santanu Banerjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2106, Bethesda, MD 20892, (301) 435-5947, banerjees5@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: May 31, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-12043 Filed 6-3-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Institute Council of Research Advocates.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov>).

Name of Committee: National Cancer Institute Council of Research Advocates.

Date: June 29, 2022.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: Welcome and Chairman's Remarks, NCI Updates, Legislative Update, and Acting Director's Update.

Place: National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Amy Williams, NCI Office of Advocacy Relations, National Cancer Institute, NIH, 31 Center Drive, Building 31, Room 10A28, Bethesda, MD 20892, (301) 496-9723, williamam@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding

the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: NCRA: <http://deainfo.nci.nih.gov/advisory/ncra/ncra.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS).

Dated: May 31, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-12042 Filed 6-3-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Proposed Reorganization

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Biomedical Imaging and Bioengineering (NIBIB) will host a public hearing to enable public discussion of the Institute's proposal to establish the Center for Biomedical Imaging and Technology Acceleration (βETA). The proposed reorganization aims to accelerate the development, validation, and dissemination of high-impact biomedical technologies to address urgent national and global health needs.

DATES: The public hearing will take place on June 29, 2022, at 2 p.m. using NIBIB's social media accounts. Any interested party may also file written comments by sending an email to NIBIBorgchange@nih.gov prior or during the scheduled public hearing. The statement should include the individual's name, and when applicable, professional affiliation.

ADDRESSES: The following email address has been established for comments on the reorganization: NIBIBorgchange@nih.gov. The social media platforms that will be used and monitored during this hearing are:

• **Twitter:** @NIBIBgov

• **Facebook:** <https://www.facebook.com/nibibgov/>

FOR FURTHER INFORMATION CONTACT: Eva Kakoza, Management Analyst, National Institute of Biomedical Imaging and Bioengineering, NIH, (301) 402-4584, NIBIBorgchange@nih.gov.

SUPPLEMENTARY INFORMATION: Pursuant to the NIH Reform Act of 2006 (42 U.S.C. Sec.281 (d)(4)), NIBIB will have a public hearing to discuss the proposed reorganization plans. This announcement and the public forum serve as that notice. More information can be found at <https://www.nibib.nih.gov/about-nibib/proposed-org-changes>.

Jason M. Ford,

Executive Officer, National Institute of Biomedical Imaging and Biomedical Engineering, National Institutes of Health.

[FR Doc. 2022-12073 Filed 6-3-22; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA DK21-012 SBIR Review.

Date: June 29, 2022.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: NIDDK, NIH, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7119, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, 301-594-2242, jerkinsa@nidk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research;